DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February 18, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-30

Richard M. Kopwitz, CEO/Secretary/Treasurer
James H. Kopwitz, President
Draper Valley Farms, Inc.
17413 State Route 20
Burlington, Washington 98233

WARNING LETTER

Dear Messrs. Kopwitz:

An inspection of your medicated feed mill located at 17413 State Route 20, Mount Vernon, Washington, conducted November 4 and 18, 1999, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR225)]. Such deviations cause medicated feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found your facility failed to collect and assay, by approved official methods, at periodic intervals during the calendar year, at least three representative samples of medicated feed containing each drug or drug combination, that require an approved Feed Mill license used at your facility, as required by 21 CFR 225.58(b)(1). For example, no assays were performed in 1998 nor 1999 on finished feeds made with the following category II type A medicated articles: a) Stenorol (halofuginone hydrobromide); b) Nicarb 25% (nicarbazin); and Roxarsone (3-Nitro-20).

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the inspection, evaluated together with the evidence before FDA when the Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packaging of medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director